

Denka: ORD Support

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ORD/NCEA

June 22, 2017

Background

- Chloroprene is used to manufacture neoprene rubber, used in car door seals, wetsuits, etc.
- IRIS assessment for chloroprene was completed in 2010 (ORD/NCEA)
 - Likely carcinogenic; cancer potency estimate = 1 in 10,000 risk at 0.2 ug/m³
 - Reference concentration = 20 ug/m³
- National Air Toxics Assessment (NATA)(OAR/Office of Air Quality Planning and Standards)
 - NATA is a nationwide screening estimate of potential risks from air toxics
 - EPA released latest NATA in December 2015, covering emissions year 2011
 - Highest risk census tract was in LaPlace, LA, due to chloroprene emissions
 - DuPont (now Denka Performance Elastomer) identified as emitting chloroprene
 - Emissions data confirmed by DuPont
 - Cancer risks ~ 800 in 1,000,000
 - Denka is the only chloroprene manufacturing company in the US
- Public concern – many news articles. EPA Office of Inspector General Hotline request
- State of Louisiana, LaPlace in St John the Baptist Parrish, and Region 6 requested OAQPS and ORD participate in public meeting in July 2016
 - Public meeting was well attended (~150) by residents, NGOs, university, EPA Region, State and local public health officials, OAQPS, ORD and Denka company representatives

EPA Actions: R6, OAQPS, ORD, OECA

- Notified staff at the Louisiana Department of Environmental Quality (LDEQ) of the potential issue and working with them to investigate;
- Discussed with the facility the chloroprene concentrations modeled in neighborhoods near the facility and the potential risk;
- Discussed potential public health risks from chloroprene to the citizens in the Parish with state and local leaders, and with environmental groups in the area;
- Worked with the LDEQ to monitor air quality in the surrounding areas to measure actual concentrations of chloroprene in the air;
 - One year of monitoring complete, levels variable and high on occasion at schools, residences
- Hosted, along with the LDEQ leadership, a community meeting (July 2016) to present information about the chloroprene emissions and ongoing state and federal actions;
- Established an extensive website to publish information about chloroprene and the activities that are occurring in the neighborhoods around the facility;
- Communicated with the state and with the company concerning installing air pollution control equipment;
- LDEQ and Denka agreed on installation of air pollution control equipment, some workplace changes already, major installation now underway
 - Monitoring data provide some indication that ambient air levels are decreasing
<https://www.epa.gov/la/laplace-st-john-baptist-parish-louisiana>

Deliberative Process / Ex. 5

IRIS Assessment

- IRIS: Chloroprene is “likely to be carcinogenic” to humans (2010)
 - National Toxicology Program (NTP) Report on Carcinogens (2005): “reasonably anticipated to be a human carcinogen”
 - International Agency for Research on Cancer (1999): “possibly carcinogenic to humans”
- EPA evaluated human epidemiological data, animal toxicology data, and evidence that chloroprene is mutagenic.
 - In studies of occupational workers, there is evidence that chloroprene causes an increased risk of liver cancer, while other studies in humans show the possibility of an increased lung cancer risk
 - In animal studies (including NTP), chloroprene has been shown to cause many different types of tumors, including tumors in the lung, circulatory system, liver, skin, and mammary gland, among others
 - Chloroprene’s chemical structure is very similar to the known human carcinogens butadiene and vinyl chloride
- Reviews of IRIS chloroprene assessment
 - Extensive Agency, Interagency (NIEHS, OMB, CEQ, DOD, ATSDR) reviews
 - Independent external peer review panel unanimously concluded chloroprene is a likely human carcinogen that acts via a mutagenic mode of action

Challenges to IRIS Assessment

- EPA/ORD/OAQPS staff met with Denka consultants (August 2016): Ken Mundt, Robinan Gentry of Ramboll Environ

- Consultants view:

"Updating the Inhalation Unit Risk (i.e., cancer potency: IUR) is warranted based on several key points

1. Epidemiological evidence may have been misinterpreted

- *Epidemiology insufficient to conclude that chloroprene causes cancer in humans*
- *Data are inadequate for determining risk estimates*

2. Previous IUR included influential adjustments and multiple upward rounding

3. Reliance on animal evidence for risk estimates requires fuller consideration of evidence of profound interspecies differences

- *Tumor incidence indicates differences in sensitivity*
- *New studies clearly demonstrate toxicokinetic differences*
- *Current best practices would indicate validated PBPK modeling (as used with VC)"*

Consultants identified several newly published studies including a novel PBPK (physiologically-based pharmacokinetic) model and combined dose-response model

ORD Evaluation of Evidence

- ORD/NCEA scientists carefully reviewed new studies and Ramboll Environ information
- ORD Conclusions:
 - Evidence from epidemiology studies show increased cancer risks
 - New toxicology studies do not alter interpretation of animal toxicology evidence, which demonstrates multiple tumor types
 - New PBPK modeling is novel, but poor model optimization and evident enzyme induction in rodents was not accounted for
 - New combined dose-response modeling relied on judgments that underestimated risks
- Independent evaluation
 - Dept of Justice toxicologist/risk assessor concurred with ORD conclusions
- New literature search conducted (June 21, 2017); no new potentially impactful studies have been recently published

Deliberative Process / Ex. 5